

Exhibit L

SHARI ALLEN O'QUINN - Direct

1 (Exhibit Number 5001 was admitted into evidence.) 02:14:04

2 BY MR. NORTH:

3 Q. Is this Dear Doctor letter -- oh.

4 MR. NORTH: Could we display this to the jury, Your
5 Honor? 02:14:15

6 THE COURT: Yes.

7 BY MR. NORTH:

8 Q. Does this specifically advise physicians what has been
9 changed in the instructions for use based upon the clinical
10 reports? 02:14:32

11 A. Yes, it does. It indicates that -- it actually summarizes
12 the changes to the IFU and indicates how the warnings and the
13 precautions in the safety sections of the IFU were updated
14 specifically to identify the risks of fracture and migration
15 and some other procedural information that we wanted to make
16 the physicians aware of that was important. 02:14:57

17 Q. Was this the only communication the company made regarding
18 the Recovery filter and possible migration incidents to
19 physicians?

20 A. I don't recall if there was some individual communications 02:15:22
21 with physicians but we did do a second letter later, a Dear
22 Colleague letter, that also went out to physicians.

23 MR. NORTH: Let's look at 5247 if we could.

24 BY MR. NORTH:

25 Q. Do you recognize this document? 02:15:53

United States District Court

SHARI ALLEN O'QUINN - Direct

1 A. Yes. That's the Dear Colleague letter that I just
2 mentioned.

02:16:05

3 Q. And before you sent -- the company sent this letter out,
4 did you have discussions with the FDA about the fact that the
5 company was going to send this letter out to physicians?

02:16:14

6 A. Yes, we did.

7 MR. NORTH: Your Honor, at this time we would tender
8 5247.

9 MR. JOHNSON: Your Honor, we did not see this on
10 their list -- oh. Never mind. I apologize. We don't have any
11 objection.

02:16:31

12 THE COURT: All right. 5247 is admitted.

13 (Exhibit Number 5247 was admitted into evidence.)

14 MR. NORTH: Could we publish it?

15 THE COURT: You may.

02:16:44

16 BY MR. NORTH:

17 Q. If we would look in the first sentence at the paragraph
18 that begins "Over the past two years." And going to the end of
19 that paragraph. Could you tell us what the company advised
20 physicians about with regard to the Recovery filter here?

02:17:21

21 A. Yes. We advised them about the risk of filter migration
22 and that some of them had been associated with interventions
23 and death and we shared that although those events had
24 occurred, they were below the rates that had been reported in
25 the Society of Interventional Radiology guidelines and that the

02:17:48

United States District Court

SHARI ALLEN O'QUINN - Direct

1 A. Yes. We noted that the patient should be returned to 02:19:46
2 their anticoagulation therapy as soon as it was deemed safe.

3 Q. And turn to the next page, page three of this document.
4 Did the company also encourage physicians to report any adverse
5 events both to the company and to the FDA? 02:20:07

6 A. Yes, we did. We provided the FDA contact information and
7 our contact information and reiterated to the physicians that
8 it was very important for them to report the events to both us
9 and to the FDA.

10 Q. Now, when the company, during your time there, would send 02:20:28
11 out a letter like this, a Dear Colleague letter or a Dear
12 Doctor letter like the previous one we saw, what sort of steps
13 did the company take to ensure that this got the widest
14 distribution or dissemination possible?

15 A. We looked at our entire customer database of anyone that 02:20:47
16 had purchased the product and sent the product out to those
17 physicians and we tracked the delivery of those letters to make
18 sure that they were delivered.

19 Q. Now, over the course of this time period in the late 2004,
20 early 2005 time frame, were you having a number of 02:21:24
21 conversations with the FDA?

22 A. Yes, I did. I had frequent communications with the FDA.

23 Q. And did you have communications that specifically
24 discussed the reports of migration with regard to the Recovery
25 filter that the company was receiving? 02:21:41

United States District Court

SHARI ALLEN O'QUINN - Direct

1 A. Yes, I did. I had frequent phone contacts with the FDA
2 where --

3 MR. O'CONNOR: Objection, Your Honor. This is
4 hearsay.

5 THE WITNESS: I have contact had reports --

6 THE COURT: Hold on, please.

7 Overruled so far. There has been nothing said about
8 the content of the conversations.

9 BY MR. NORTH:

10 Q. Just generally, describe what these conversations were,
11 the topics of these conversations.

12 A. Yeah. The topics of the conversations were to update FDA
13 on the current rates. We would always talk about the rates.
14 We would talk about where we were in the investigation and any
15 additional work that we were doing like feedback from
16 physicians or any internal testing that we were doing, we would
17 share that with the -- I would share that with the FDA.

18 Q. Now, there has been a reference, I think you just
19 referenced it, to the SIR guidelines?

20 A. Yes.

21 Q. What are those?

22 MR. O'CONNOR: Objection, Your Honor. Lack of
23 foundation. This is not a medical doctor.

24 THE COURT: You just have to state the objection.
25 Sustained. You have to lay foundation for that.

United States District Court